

Food and Drug Administration, HHS

§ 172.381

(NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/

[code_of_federal_regulations/ibr_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) The additive may be used as follows:

Category of Food	Maximum Levels in Food (as Served)
Soy beverages	50 International Units (IU)/100 grams (g)
Soy beverage products	89 IU/100 g
Soy-based butter substitute spreads	330 IU/100 g
Soy-based cheese substitutes and soy-based cheese substitute products	270 IU/100 g

[74 FR 11022, Mar. 16, 2009]

§ 172.380 Vitamin D₃:

Vitamin D₃ may be used safely in foods as a nutrient supplement defined under § 170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D₃, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D₃ occurs in and is isolated from fish liver oils. It also is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization.

(b) Vitamin D₃ meets the specifications of the *Food Chemicals Codex*, 5th ed. (2004), pp. 498-499, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 500 Fifth St. NW., Washington, DC 20001 (Internet address <http://www.nap.edu>). Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) The additive may be used as follows:

(1) At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as de-

fined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 33 percent of the reference daily intake (RDI) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

(2) At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 10 percent of the RDI of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

(3) At levels not to exceed 140 IU per 240 mL (prepared beverage) in soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight in accordance with § 105.66 of this chapter.

(4) At levels not to exceed 100 IU per 40 grams in meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight in accordance with § 105.66 of this chapter.

(5) At levels not to exceed 81 IU per 30 grams in cheese and cheese products as defined under § 170.3(n)(5) of this chapter, excluding cottage cheese, ricotta cheese, and hard grating cheeses such as Parmesan and Romano as defined in §§ 133.165 and 133.183 of this chapter, and those defined by standard of identity in § 133.148 of this chapter.

[68 FR 9003, Feb. 27, 2003, as amended at 70 FR 36025, June 22, 2005; 70 FR 37257, June 29, 2005; 70 FR 69438, Nov. 16, 2005]

§ 172.381 Vitamin D₂ bakers yeast.

Vitamin D₂ bakers yeast may be used safely in foods as a source of vitamin

§ 172.385

21 CFR Ch. I (4–1–13 Edition)

D₂ and as a leavening agent in accordance with the following prescribed conditions:

(a) Vitamin D₂ bakers yeast is the substance produced by exposing bakers yeast (*Saccharomyces cerevisiae*) to ultraviolet light, resulting in the photochemical conversion of endogenous ergosterol in bakers yeast to vitamin D₂ (also known as ergocalciferol or (9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol)).

(b) Vitamin D₂ bakers yeast may be used alone as an active dry yeast concentrate or in combination with conventional bakers yeast.

(c) The additive may be used in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods at levels not to exceed 400 International Units of vitamin D₂ per 100 grams in the finished food.

(d) To assure safe use of the additive, the label or labeling of the food additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

(e) Labels of manufactured food products containing the additive shall bear, in the ingredient statement, the name of the additive, "vitamin D₂ bakers yeast," in the proper order of decreasing predominance in the finished food.

[77 FR 52231, Aug. 29, 2012]

§ 172.385 Whole fish protein concentrate.

The food additive whole fish protein concentrate may be safely used as a food supplement in accordance with the following prescribed conditions:

(a) The additive is derived from whole, wholesome hake and hakelike fish, herring of the genera *Clupea*, menhaden, and anchovy of the species *Engraulis mordax*, handled expeditiously and under sanitary conditions in accordance with good manufacturing practices recognized as proper for fish that are used in other forms for human food.

(b) The additive consists essentially of a dried fish protein processed from the whole fish without removal of heads, fins, tails, viscera, or intestinal

contents. It is prepared by solvent extraction of fat and moisture with isopropyl alcohol or with ethylene dichloride followed by isopropyl alcohol, except that the additive derived from herring, menhaden and anchovy is prepared by solvent extraction with isopropyl alcohol alone. Solvent residues are reduced by conventional heat drying and/or microwave radiation and there is a partial removal of bone.

(c) The food additive meets the following specifications:

(1) Protein content ($N \times 6.25$) shall not be less than 75 percent by weight of the final product, as determined by the method described in section 2.057 in "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980). Protein quality shall not be less than 100, as determined by the method described in sections 43.212–43.216 of the AOAC. The 13th Ed. is incorporated by reference, and copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) Moisture content shall not exceed 10 percent by weight of the final product, as determined by the method described in section 24.003 of the AOAC. See paragraph (c)(1) of this section for availability of the material incorporated by reference.

(3) Fat content shall not exceed 0.5 percent by weight of the final product, as determined by the method described in section 24.005 of the AOAC. See paragraph (c)(1) of this section for availability of the material incorporated by reference.

(4) The additive may contain residues of isopropyl alcohol and ethylene dichloride not in excess of 250 parts per million and 5 parts per million, respectively, when used as solvents in the extraction process.

(5) Microwave radiation meeting the requirements of § 179.30 of this chapter